Developing Guidance on Naming, Labeling, and Packaging Practices to Minimize Medication Errors

Public Workshop – June 24-25, 2010

Docket No. FDA-2010-N-0168

Center for Drug Evaluation and Research (CDER) Food and Drug Administration (FDA) Department of Health and Human Services

AGENDA

June 24, 2010	DAY ONE
8:30 am	Opening Remarks Gerald Dal Pan, MD, MHS Director, FDA Office of Surveillance and Epidemiology (OSE)
8:35 am	Logistics Carol Holquist, RPh Director, Division of Medication Error Prevention and Analysis, OSE
8:40 – 8:50 am	FDA Presentation and Panel 1 Introduction Kellie Taylor, Pharm D, MPH Associate Director, Division of Medication Error Prevention and Analysis, OSE
8:50 – 9:20 am	FDA Panel 1A: Container Label and Carton Labeling Design to Reduce Medication Error Carol Holquist, RPh
9:20 – 9:50 am	FDA Panel 1B: Container Label and Carton Labeling Design to Reduce Medication Error Carol Holquist, RPh
9:50 – 10:05 am	BREAK
10:05 – 11:05 am	Open Public Session
11:05 – 11:15 am	FDA Presentation and Panel 2 Introduction Kellie Taylor, Pharm D, MPH
11:15 am – 12:00 pm	Panel 2: Study Design, Conduct and Interpretation to Reduce Medication Errors Carol Holquist, RPh
12:00 – 1:00 pm	LUNCH (On your own)
1:00 – 2:00 pm	Open Public Session
2:00 – 2:10 pm	FDA Presentation and Panel 3 Introduction Kellie Taylor, Pharm D, MPH
2:10 – 2:25 pm	BREAK
2:25 – 3:10 pm	Panel 3: Manufacturers' Packaging to Reduce Medication Errors Carol Holquist, RPh
3:10 – 4:00 pm	Open Public Session
4:00 pm	Conclusion Day 1

June 25, 2010	DAY TWO
8:30 am	Opening Remarks Gerald Dal Pan, MD, MHS
8:35 – 8:45 am	FDA Presentation and Panel 4 Introduction Kellie Taylor, Pharm D, MPH
8:45 – 10:00 am	Panel 4: Practices to Develop Testing of Proprietary Names to Reduce Medication Errors Carol Holquist, RPh
10:00 – 10:15 am	BREAK
10:15 – 11:15 am	Open Public Session
12:00 pm	Conclusion Carol Holquist, RPh

Please be advised that as soon as a transcript is available, it will be accessible at http://www.regulations.gov and http://www.fda.gov/Drugs/NewsEvents/

Written and electronic comments will be accepted after the hearing until July 23, 2010. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1051, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov.